Ti-TaMED (PTY) LTD
MANUFACTURERS OF QUALITY SURGICAL IMPLANTS

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K070385

510(k) Summary:

Contact: Sandi Ashbury
Company Correspondent

JUL 31 2009

29 July 2009

Trade name: Ti-TaMED Spinal System

Common Name: Spinal Fixation Device

Classification Name: Spinal Interlaminal Fixation Orthosis, Spondylolisthesis Spinal fixation Device System, Pedicle Screw Fixation System.

Equivalent device: Moss Miami Spinal System – DePuy Acromed, Inc. K022623
Polaris 5.5 – Biomet Spine. K081952

Product Description:

The Ti-TaMED Spinal System consists of a variety of rods, hooks, screws, cross connectors and other connecting components used to build a spinal construct. Instrumentation is also available to facilitate implantation of the device components.

The System consists of four types of screws all manufactured out of Titanium (6A 1-4V ELI).

1. Poly Axial Screws: These screws have a poly axial articulation that allows angulations of the head in all directions, but once the cap or grub screw and ring are tightened the position becomes locked.

Dimensions / sizes:

- 5 mm diameter (Ø)(30mm lengths to 45 mm's)
- 6 mm Ø (30 mm to 50 mm)
- 7 mm Ø (30 mm to 50 mm)

2. Rigid screws:
   Dimensions/sizes:

- 5 mm Ø (35 mm to 45 mm)
- 6 mm Ø (35 mm to 50 mm)
- 7 mm Ø (30 mm to 50 mm)
- 8 mm Ø (40 mm to 55 mm)

The Ti-TaMED Spinal system consists of two different types of rods:

Round both ends
- 5.5 mm Ø (30 mm to 1000 mm)

Round and hexagonal ends
- 5.5 mm Ø (30 mm to 1000 mm)

The Ti-TaMED Spinal system also consists of the following:

Cross Connector:
The Cross Connector is a device that links 2 vertical Ti-TaMED Connecting Rods to each other, thereby fulfilling the purpose of increasing torsional stiffness of a construct. The design includes the ability to accommodate non perpendicular connections between the Cross Connector and the Connecting Rods.

A complete Cross Connector is a unit comprising 2 each of the following: Body, Cap, Screw, Nut and Rod.

Dimensions / sizes:

- Only one size exists: the diameter of the cap is 14mm and the length of Rods are 60mm to 90mm

Hooks

6 types:
1) Pedicle Std. Straight
2) Laminar small straight
3) Laminar large straight
4) Laminar small angled
5) Laminar left offset
6) Laminar right offset

- grub screw and ring one size

Screw caps

1 type of cap (M10X1 thread) is used on all screws.
1 type of grub screw and ring is used on all screws.

The Ti-TaMED screws and rods may be used posteriorly or anteriorly to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or lumbar spine. The Ti-TaMED spinal implant components can be rigidly locked into a variety of configurations, with each case being tailor made for the individual.

The Ti-TaMED hooks and cross connectors are intended for posterior only, where as all other components may be used anteriorly or posteriorly.

Indications for use:

The Ti-TaMED Spinal System is intended for immobilization and stabilization of the spine as an adjunct to fusion for use in anterior, anterolateral, or posterior non-cervical pedicle and non-pedicle fixation for spinal conditions in skeletally mature patients with significant mechanical instability or deformity requiring fusion of the thoracic, lumbar or sacral spine secondary to the following conditions: Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ti-TaMed (PTY) LTD
% Ms. Sandra Mortimer
54 Auckland Street Paarden Eiland
Cape Town, Western Cape
South Africa 7405

JUL 31 2009

Re: K070385
Trade/Device Name: Ti-TaMED Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH, KWQ
Dated: April 30, 2009
Received: April 30, 2009

Dear Ms. Mortimer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

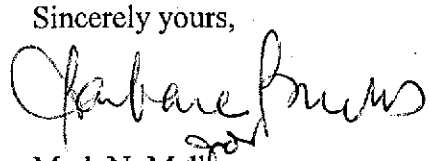
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k070385

Device Name: Ti-TaMED Spinal System

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Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K070385